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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,904	01/18/2002	Janice Au-Young	PF-0723 USN	8248

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LEGAL DEPARTMENT
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EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,904	AU-YOUNG ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,15-17,19,22,25,26 and 28* is/are pending in the application.

4a) Of the above claim(s) *1,2,8,10,13,15-17,19,22,25,26 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7,9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11,13,15-17,19,22,25,26 and 28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of Group II (Claims 3-7, 9, and 11) in Paper No. 7 filed on September 3, 2002 is acknowledged. Applicants' election with traverse of the polynucleotides sequence encoding the polypeptide sequence of SEQ ID NO: 8, which includes SEQ ID NO:30, is also acknowledged.

The traverse is on the grounds (i) that the claimed polypeptide sequences and the claimed polynucleotides sequences which encode them are corresponding technical features which are common to all of applicants claims, which serve to technically interrelate all of applicants' claims, and which define the contribution over the prior art made by each of them. Thus, applicants' claims are linked to form a single general inventive concept, and applicants are therefore entitled to prosecute all of their pending claims in a single national stage application (3rd paragraph of page 12 of applicants' response) and (ii) SEQ ID NOS: 15 and 16 (or SEQ ID NOS: 10 and 12) are alternatives of a similar nature which should also be examined in a single application (pages 14-15 of applicants response).

Applicants' lengthy argument has been fully considered but is not deemed to be persuasive for the following reasons. As stated in the restriction requirement set forth in previous office action (Paper No. 3, June 19, 2002), the inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1

because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XIV appears to be the claimed amino acid/nucleic acid sequences. However, Claims 1, 3-7, 9, 11, and 12 are anticipated by Seol et al. (EMBL database, Accession No. U22015, March, 15, 1995; Seol et al, Mol. Endocrinol. 9(1), 72-85, 1995) or by Strausberg et al. (EMBL database, Accession No. AI337112, December 31, 1998). The references teach a polypeptide fragment of SEQ ID NO: 1.

Therefore, the technical feature linking the inventions of Groups I-XIV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

In addition, each of the sequences represents a structurally and functionally distinct entity. The search and consideration of all of the sequences constitutes an undue search burden on the office, given the ever-increasing size of the database.

The requirement is still deemed proper and is therefore made FINAL.

Response to Applicants' Amendment

2. Applicants' amendment in Paper No. 8 filed on September 3, 2002 has been entered in full. Claims 1-11,13,15-17,19, 22, 25, 26, and 28 are pending. Claim 1 has been amended. Claims 3-7, 9, and 11 are under consideration. All other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to provisional applications, 60/145,232 (filed on 07/21/1999), 60/158,578 (filed on 10/07/1999), and 60/165,192 (filed on 11/12/1999).

Rejections—35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 3-7, 9, and 11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 3-7, 9, and 11 are drawn to an isolated polynucleotide, host cell, and a method of producing a polypeptide. The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not requires further research.

The instant disclosure asserts that the polypeptide of SEQ ID NO: 8 encoded by the polynucleotide of SEQ ID NO:30 is related to receptors (line 17 of page 6). However, the instant disclosure fails to disclose any biological functions or activities

of the claimed polypeptide. There is no specific and substantial utility disclosed in the instant disclosure.

The instant disclosure asserts that the present invention provides a method for detecting a target polynucleotide in a sample comprising hybridization of the sample with a probe prepared from the disclosed polynucleotides (1st paragraph of page 8) or by amplifying the target polynucleotide using PCR technique with primers prepared from the disclosed polynucleotide sequence (3rd paragraph of page 8). The instant disclosure also asserts that the present invention provides methods for screening an agonist, an antagonist, or compound which binds to the claimed polypeptide, modulates the activity of the claimed polypeptide or the expression of a target polynucleotide (bottom of page 8 to top of page 10). However, such uses are all considered research uses only designed to identify a particular function of the claimed molecules and are not a substantial utility. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility." Moreover, such uses are not specific to the instant molecule but rather applicable to any nucleic acids or proteins.

The instant disclosure further asserts that the present invention provides a pharmaceutical composition comprising the claimed polypeptide, an agonist, an antagonist, and provides a method of treating a disease or condition associated with aberrant expression of the claimed polypeptide using such a composition (4th paragraph of page 8 to 2nd paragraph of page 9). These asserted utilities are not specific and substantial because they do not identify or reasonably confirm a "real world" context of use. The disclosure neither identifies the biological functions of the

claimed proteins nor any disorders that are associated with the claimed molecules. Clearly, further research would be required to determine the functions of the claimed molecules or to identify a disease that can be treated or diagnosed with the claimed molecules See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. No art of record discloses or suggests any property or activity for the claimed molecules such that another non-asserted utility would be well-established for the compounds.

6. Claims 3-7, 9, and 11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, even if the polynucleotide sequence set forth in SEQ ID NO: 30 which encodes the polypeptide of SEQ ID NO: 8 were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed invention.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the

relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 3, 6, 7, and 9 as written recite a genus of polynucleotides encoding (i) an isolated polypeptide comprising an amino acid sequences having at least 90% sequence identity to SEQ ID NO:8 or (ii) fragments of SEQ ID NO: 8, whereas claim 11 recites a genus of polynucleotides comprising a polynucleotide sequence which has at least 70% sequence identity to SEQ ID NO:30.

However, other than the polynucleotide sequence of SEQ ID NO: 30 encoding the polypeptide of SEQ ID NO: 8, the disclosure fails to provide sufficient guidance, information or working examples regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claims. The disclosure does not show (i) which portions of SEQ ID NO: 8 are critical to the activity of the polypeptide of SEQ ID NO:8; and (ii) what modifications (e.g., substitutions, deletions or additions) one can make to SEQ ID NO: 30 will result in protein mutants with the same functions as the claimed polypeptide of SEQ ID NO:8. The state of the art (See, e.g., Ngo, et al, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz, et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495) is such that the relationship between sequence of a protein and its activity is not well understood and is not predictable. Excising out portions of a protein or modifications to a protein, e.g., by substitutions or deletions, would often result in deleterious effects to the overall activity and effectiveness of the protein.

Furthermore, the term, "biologically active", as defined in the instant disclosure

(bottom of page 13), refers to a protein having structural, regulatory, or biochemical functions of a naturally occurring molecule. Thus, the term is so broad that it encompasses any function or activity of a protein. However, the instant disclosure fails to discloses any function of the polypeptide set forth in SEQ ID NO:8 encoded by SEQ ID NO:30.

Since the disclosure fails to provide sufficient guidance and information to enable one skilled in the art to predict which if any fragments of the whole molecule would be reasonably expected to retain characteristic activities alone and the general disclosure that one could make and use SEQ ID NO:8 or SEQ ID NO:30 could not be used to be such guidance as to guide one skilled in the art to make and use the invention commensurate in scope with the claims, the disclosure fails to enable such a myriad of the claimed nucleic acid molecules and polypeptides that not only vary substantially in length but also in amino acid composition and to provide any guidance to one skilled in the art on how to make and use the claimed polynucleotides and polypeptides. Thus, it would require undue experimentation for one skilled in the art to make and use the claimed genus of polynucleotides and polypeptides embraced by the instant claims.

Claim Rejections—35 USC § 112, 1st paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 3, 6, 7, 9, and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The description discloses a nucleotide sequence set forth in SEQ ID NO: 30, which encodes a polypeptide of SEQ ID NO: 8. However, claims 3, 6, 7, and 9 as written recite a genus of polynucleotides encoding (i) an isolated polypeptide comprising an amino acid sequences having at least 90% sequence identity to SEQ ID NO:8 or (ii) fragments of SEQ ID NO: 8, whereas claim 11 recites a genus of polynucleotides comprising a polynucleotide sequence which has at least 70% sequence identity to SEQ ID NO:30. Thus, the claims encompass a huge number of nucleic acids that vary substantially both in length and in nucleotide composition.

The instant disclosure of a polynucleotide sequence of SEQ ID NO: 30 that encodes the polypeptide of SEQ ID NO: 2 does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant disclosure fails to provide sufficient description information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions that are critical to

the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Since there is no disclosure on the biological functions of the claimed molecules, the functional limitation, "biologically active" or "immunogenic" does not effectively limit the scope of the claimed invention. Furthermore, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed polynucleotides as being identical to those instantly claimed.

Due to the breadth of the claim genus and lack of the definitive structural or functional features of the claimed genus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus.

Claim Rejections—35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 3, 6, 7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Fearon e t al. (U. S. Patent No. 5,981,481, November 9, 1999, filed on June 6, 1995).

Fearon et al. teach an isolated polynucleotide encoding a polypeptide, human C3b/C4b receptor (CR1; see Abstract; bottom of column 11 to top of column 12), which shares 81% identity with SEQ ID NO: 8 at the amino acid level (see attached sequence alignment). Fearon et al. also teach polynucleotides encoding fragments of CR1. The CR1 protein and its fragments bind C3b and C4b that have covalently attached to immune complexes and other complement activators, and inhibit factor I cofactor activity (See, e.g., 3rd paragraph of column 4; 2nd paragraph of column 12). Thus, CR1 protein and its fragments are biologically active and immunogenic.

Fearon et al. further teach methods of expressing CR1 protein (column 34) and its fragments (column 35) in COS cells transformed with mammalian expression vectors including piABCD, piBCDpiABD, piAd, piBD, and PiCD (See, example 8; claims 39, 41, and 42), and production and purification of soluble CR1 (example 12, column 51). Thus, the reference of Fearon et al. meet the limitations of claims 3, 6, 7, and 9.

Claim Objections—Minor Informalities

11. Claims 3-7 and 9 are objected to because they recite unelected subject matter (nucleic acid/amino acid sequences) and depend upon unelected claims (claims 1 and 2). Appropriate correction is required.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
October 31, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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